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**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

GARY ZIEROTH, as representative of the estate
of SHARON ZIEROTH,

Plaintiff,

v.

ALEX M. AZAR II, in his official capacity as
Secretary of Health and Human Services,

Defendant.

Case No. 3:20-cv-172 (MMC)

**ANSWER TO THE
FIRST AMENDED COMPLAINT**

1 The Defendant, Alex M. Azar II, Secretary of Health and Human Services (the
2 “Secretary”), respectfully answers the allegations of the First Amended Complaint as
3 follows. The Secretary notes that, pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s
4 review in this action is based solely on the administrative record, rather than the
5 allegations of the parties in their respective pleadings.

6 1. This paragraph consists of Plaintiff’s legal conclusions and
7 characterization of this lawsuit, to which no response is required.

8 2. This paragraph consists of Plaintiff’s legal conclusions regarding subject-
9 matter jurisdiction, to which no response is required.

10 3. This paragraph consists of Plaintiff’s legal conclusions regarding venue, to
11 which no response is required.

12 4. Admitted.

1 5. Admitted that Alex M. Azar II is the Secretary of Health and Human
2 Services. The remainder of this paragraph consists of Plaintiff's characterization of this
3 lawsuit, to which no response is required.

4 6. Defendant is without knowledge or information sufficient to confirm or
5 deny the allegations contained in the first sentence. The second sentence consists of
6 Plaintiff's legal conclusions regarding intradistrict assignment, to which no response is
7 required.

8 7. This paragraph consists of factual allegations regarding diabetes. Pursuant
9 to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the
10 administrative record, rather than the allegations of the parties in their respective
11 pleadings; Defendant thus respectfully refers the Court to the administrative record for a
12 full and accurate statement of its contents. To the extent that these allegations are not
13 reflected in the administrative record, they are beyond the scope of the Court's review in
14 this case, and no response is required.

15 8. This paragraph consists of factual allegations regarding diabetes. Pursuant
16 to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the
17 administrative record, rather than the allegations of the parties in their respective
18 pleadings; Defendant thus respectfully refers the Court to the administrative record for a
19 full and accurate statement of its contents. To the extent that these allegations are not
20 reflected in the administrative record, they are beyond the scope of the Court's review in
21 this case, and no response is required.

22 9. This paragraph consists of factual allegations regarding diabetes and the
23 late Plaintiff's medical condition. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's

1 review in this action is based solely on the administrative record, rather than the
2 allegations of the parties in their respective pleadings; Defendant thus respectfully refers
3 the Court to the administrative record for a full and accurate statement of its contents. To
4 the extent that these allegations are not reflected in the administrative record, they are
5 beyond the scope of the Court's review in this case, and no response is required.

6 10. This paragraph consists of factual allegations regarding diabetes and the
7 late Plaintiff's medical condition. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's
8 review in this action is based solely on the administrative record, rather than the
9 allegations of the parties in their respective pleadings; Defendant thus respectfully refers
10 the Court to the administrative record for a full and accurate statement of its contents. To
11 the extent that these allegations are not reflected in the administrative record, they are
12 beyond the scope of the Court's review in this case, and no response is required.

13 11. This paragraph consists of factual allegations regarding diabetes and the
14 late Plaintiff's medical condition. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's
15 review in this action is based solely on the administrative record, rather than the
16 allegations of the parties in their respective pleadings; Defendant thus respectfully refers
17 the Court to the administrative record for a full and accurate statement of its contents. To
18 the extent that these allegations are not reflected in the administrative record, they are
19 beyond the scope of the Court's review in this case, and no response is required.

20 12. This paragraph consists of factual allegations regarding diabetes. Pursuant
21 to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the
22 administrative record, rather than the allegations of the parties in their respective
23 pleadings; Defendant thus respectfully refers the Court to the administrative record for a

1 full and accurate statement of its contents. To the extent that these allegations are not
2 reflected in the administrative record, they are beyond the scope of the Court's review in
3 this case, and no response is required.

4 13. This paragraph consists of factual allegations regarding diabetes. Pursuant
5 to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely on the
6 administrative record, rather than the allegations of the parties in their respective
7 pleadings; Defendant thus respectfully refers the Court to the administrative record for a
8 full and accurate statement of its contents. To the extent that these allegations are not
9 reflected in the administrative record, they are beyond the scope of the Court's review in
10 this case, and no response is required.

11 14. This paragraph consists of allegations regarding the treatment of diabetes
12 in Medicare beneficiaries. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in
13 this action is based solely on the administrative record, rather than the allegations of the
14 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
15 administrative record for a full and accurate statement of its contents. To the extent that
16 these allegations are not reflected in the administrative record, they are beyond the scope
17 of the Court's review in this case, and no response is required. The Court is respectfully
18 referred to the referenced CMS decision memo for a full and complete statement of its
19 contents.

20 15. This paragraph consists of factual allegations regarding glucose tests.
21 Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely
22 on the administrative record, rather than the allegations of the parties in their respective
23 pleadings; Defendant thus respectfully refers the Court to the administrative record for a

1 full and accurate statement of its contents. To the extent that these allegations are not
2 reflected in the administrative record, they are beyond the scope of the Court's review in
3 this case, and no response is required.

4 16. This paragraph consists of factual allegations regarding glucose tests.
5 Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely
6 on the administrative record, rather than the allegations of the parties in their respective
7 pleadings; Defendant thus respectfully refers the Court to the administrative record for a
8 full and accurate statement of its contents. To the extent that these allegations are not
9 reflected in the administrative record, they are beyond the scope of the Court's review in
10 this case, and no response is required.

11 17. This paragraph consists of factual allegations regarding continuous
12 glucose monitors.¹ Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
13 action is based solely on the administrative record, rather than the allegations of the
14 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
15 administrative record for a full and accurate statement of its contents. To the extent that
16 these allegations are not reflected in the administrative record, they are beyond the scope
17 of the Court's review in this case, and no response is required.

18 18. This paragraph consists of factual allegations regarding continuous
19 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
20 action is based solely on the administrative record, rather than the allegations of the
21 parties in their respective pleadings; Defendant thus respectfully refers the Court to the

¹ In this paragraph, and throughout much of the remainder of the First Amended Complaint, Plaintiff refers to a "COM," which the Secretary understands to be a typographical error for "CGM," or "continuous glucose monitor."

1 administrative record for a full and accurate statement of its contents. To the extent that
2 these allegations are not reflected in the administrative record, they are beyond the scope
3 of the Court's review in this case, and no response is required.

4 19. This paragraph consists of a factual allegation regarding continuous
5 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
6 action is based solely on the administrative record, rather than the allegations of the
7 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
8 administrative record for a full and accurate statement of its contents. To the extent that
9 this allegation is not reflected in the administrative record, it is beyond the scope of the
10 Court's review in this case, and no response is required.

11 20. This paragraph consists of factual allegations regarding continuous
12 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
13 action is based solely on the administrative record, rather than the allegations of the
14 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
15 administrative record for a full and accurate statement of its contents. To the extent that
16 these allegations are not reflected in the administrative record, they are beyond the scope
17 of the Court's review in this case, and no response is required.

18 21. This paragraph consists of factual allegations regarding continuous
19 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
20 action is based solely on the administrative record, rather than the allegations of the
21 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
22 administrative record for a full and accurate statement of its contents. To the extent that
23 these allegations are not reflected in the administrative record, they are beyond the scope

1 of the Court's review in this case, and no response is required.

2 22. This paragraph consists of factual allegations regarding continuous
3 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
4 action is based solely on the administrative record, rather than the allegations of the
5 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
6 administrative record for a full and accurate statement of its contents. To the extent that
7 these allegations are not reflected in the administrative record, they are beyond the scope
8 of the Court's review in this case, and no response is required.

9 23. This paragraph consists of factual allegations regarding continuous
10 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
11 action is based solely on the administrative record, rather than the allegations of the
12 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
13 administrative record for a full and accurate statement of its contents. To the extent that
14 these allegations are not reflected in the administrative record, they are beyond the scope
15 of the Court's review in this case, and no response is required.

16 24. This paragraph consists of factual allegations regarding continuous
17 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
18 action is based solely on the administrative record, rather than the allegations of the
19 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
20 administrative record for a full and accurate statement of its contents. To the extent that
21 these allegations are not reflected in the administrative record, they are beyond the scope
22 of the Court's review in this case, and no response is required.

23 25. This paragraph consists of factual allegations regarding continuous

1 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
2 action is based solely on the administrative record, rather than the allegations of the
3 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
4 administrative record for a full and accurate statement of its contents. To the extent that
5 these allegations are not reflected in the administrative record, they are beyond the scope
6 of the Court's review in this case, and no response is required.

7 26. This paragraph consists of factual allegations regarding continuous
8 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
9 action is based solely on the administrative record, rather than the allegations of the
10 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
11 administrative record for a full and accurate statement of its contents. To the extent that
12 these allegations are not reflected in the administrative record, they are beyond the scope
13 of the Court's review in this case, and no response is required.

14 27. This paragraph consists of plaintiff's characterizations and legal
15 conclusions regarding the treatment of continuous glucose monitors under Medicare Part
16 B, to which no response is required.

17 28. This paragraph consists of plaintiff's characterizations and legal
18 conclusions regarding Medicare Part B, to which no response is required. The Court is
19 respectfully referred to the cited statutory provision for a full and complete statement of
20 its contents.

21 29. This paragraph consists of plaintiff's characterizations and legal
22 conclusions regarding the Secretary's regulations, to which no response is required. The
23 Court is respectfully referred to the cited regulatory provision for a full and complete

1 statement of its contents.

2 30. This paragraph consists of a block quotation of a statutory provision, to
3 which no response is required. The Court is respectfully referred to the cited statutory
4 provision for a full and complete statement of its contents.

5 31. This paragraph consists of plaintiff's characterizations and legal
6 conclusions regarding a statutory provision, to which no response is required. The Court
7 is respectfully referred to the cited statutory provision for a full and complete statement
8 of its contents.

9 32. Defendant admits that CMS Ruling 1682-R was issued on January 12,
10 2017. The remainder of this paragraph consists of plaintiff's characterizations and legal
11 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
12 is respectfully referred to the cited CMS Ruling for a full and complete statement of its
13 contents.

14 33. This paragraph consists of plaintiff's quotation from CMS Ruling 1682-R,
15 to which no response is required. The Court is respectfully referred to the cited CMS
16 Ruling for a full and complete statement of its contents.

17 34. This paragraph consists of plaintiff's characterizations and legal
18 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
19 is respectfully referred to the cited CMS Ruling for a full and complete statement of its
20 contents.

21 35. This paragraph consists of plaintiff's characterizations and legal
22 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
23 is respectfully referred to the cited CMS Ruling for a full and complete statement of its

1 contents.

2 36. This paragraph consists of plaintiff's characterizations and legal
3 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
4 is respectfully referred to the cited CMS Ruling for a full and complete statement of its
5 contents.

6 37. This paragraph consists of plaintiff's characterizations and legal
7 conclusions regarding the treatment of continuous glucose monitors under Medicare Part
8 B, to which no response is required.

9 38. This paragraph consists of plaintiff's characterizations and legal
10 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
11 is respectfully referred to the cited CMS Ruling for a full and complete statement of its
12 contents.

13 39. This paragraph consists of plaintiff's characterizations and legal
14 conclusions regarding LCD L33822 and Policy Article A52464, to which no response is
15 required. The Court is respectfully referred to the cited local coverage determination and
16 policy article for a full and complete statement of their contents.

17 40. This paragraph consists of plaintiff's characterizations and legal
18 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
19 is respectfully referred to the cited CMS Ruling for a full and complete statement of its
20 contents.

21 41. This paragraph consists of plaintiff's characterizations and legal
22 conclusions regarding National Coverage Determination 280.1, among other things. No
23 response is required. The Court is respectfully referred to the cited national coverage

1 determination for a full and complete statement of its contents.

2 42. This paragraph consists of plaintiff's characterizations and legal
3 conclusions regarding Local Coverage Determination L33822 and Policy Article
4 A52464, among other things. No response is required. The Court is respectfully referred
5 to the cited local coverage determination and policy article for a full and complete
6 statement of their contents.

7 43. Admitted that several district courts have reviewed Medicare Part B
8 coverage determinations for continuous glucose monitors.

9 44. This paragraph consists of plaintiff's characterizations and legal
10 conclusions regarding several district court decisions, to which no response is required.
11 The Court is respectfully referred to those district court decisions for a full and complete
12 statement of their contents.

13 45. This paragraph consists of plaintiff's characterizations and legal
14 conclusions regarding several district court decisions, to which no response is required.
15 The Court is respectfully referred to those district court decisions for a full and complete
16 statement of their contents.

17 46. This paragraph consists of plaintiff's characterizations and legal
18 conclusions regarding the district court's decision in *Whitcomb v. Azar*, to which no
19 response is required. The Court is respectfully referred to that decision for a full and
20 complete statement of its contents.

21 47. This paragraph consists of plaintiff's characterizations and legal
22 conclusions regarding several district court decisions, to which no response is required.
23 The Court is respectfully referred to those district court decisions for a full and complete

1 statement of their contents.

2 48. This paragraph consists of plaintiff's characterizations and legal
3 conclusions regarding a decision of the Departmental Appeals Board, to which no
4 response is required. The Court is respectfully referred to the cited decision for a full and
5 complete statement of its contents.

6 49. This paragraph consists of plaintiff's characterizations and legal
7 conclusions regarding a statutory provision, to which no response is required. The Court
8 is respectfully referred to the cited provision for a full and complete statement of its
9 contents. To the extent that a response is required, the Secretary denies that the
10 continuous glucose monitor at issue in this case is either durable medical equipment or a
11 prosthetic device within the meaning of the Medicare Act.

12 50. This paragraph consists of plaintiff's quotation from a Medicare manual
13 provision, to which no response is required. The Court is respectfully referred to that
14 manual provision for a full and complete statement of its contents.

15 51. This paragraph consists of plaintiff's characterizations and legal
16 conclusions regarding a Medicare manual provision, to which no response is required.
17 The Court is respectfully referred to that manual provision for a full and complete
18 statement of its contents. To the extent that a response is required, the Secretary denies
19 that the continuous glucose monitor at issue in this case is either durable medical
20 equipment or a prosthetic device within the meaning of the Medicare Act.

21 52. This paragraph consists of factual allegations regarding the late Plaintiff.
22 Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely
23 on the administrative record, rather than the allegations of the parties in their respective

1 pleadings; Defendant thus respectfully refers the Court to the administrative record for a
2 full and accurate statement of its contents. To the extent that these allegations are not
3 reflected in the administrative record, they are beyond the scope of the Court's review in
4 this case, and no response is required.

5 53. This paragraph consists of factual allegations regarding the late Plaintiff.
6 Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely
7 on the administrative record, rather than the allegations of the parties in their respective
8 pleadings; Defendant thus respectfully refers the Court to the administrative record for a
9 full and accurate statement of its contents. To the extent that these allegations are not
10 reflected in the administrative record, they are beyond the scope of the Court's review in
11 this case, and no response is required.

12 54. This paragraph consists of factual allegations regarding the late Plaintiff.
13 Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this action is based solely
14 on the administrative record, rather than the allegations of the parties in their respective
15 pleadings; Defendant thus respectfully refers the Court to the administrative record for a
16 full and accurate statement of its contents. To the extent that these allegations are not
17 reflected in the administrative record, they are beyond the scope of the Court's review in
18 this case, and no response is required.

19 55. This paragraph consists of factual allegations regarding the late Plaintiff
20 and her continuous glucose monitor. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the
21 Court's review in this action is based solely on the administrative record, rather than the
22 allegations of the parties in their respective pleadings; Defendant thus respectfully refers
23 the Court to the administrative record for a full and accurate statement of its contents. To

1 the extent that these allegations are not reflected in the administrative record, they are
2 beyond the scope of the Court's review in this case, and no response is required.

3 56. This paragraph consists of allegations regarding the coverage claim at
4 issue in this case. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
5 action is based solely on the administrative record, rather than the allegations of the
6 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
7 administrative record for a full and accurate statement of its contents. To the extent that
8 these allegations are not reflected in the administrative record, they are beyond the scope
9 of the Court's review in this case, and no response is required.

10 57. This paragraph consists of allegations regarding the coverage claim at
11 issue in this case. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
12 action is based solely on the administrative record, rather than the allegations of the
13 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
14 administrative record for a full and accurate statement of its contents. To the extent that
15 these allegations are not reflected in the administrative record, they are beyond the scope
16 of the Court's review in this case, and no response is required.

17 58. Admitted that the late Plaintiff's claims for coverage were initially denied
18 on the listed dates, and that she sought redetermination. The remainder of this paragraph
19 consists of Plaintiff's characterization of those initial denials, to which no response is
20 required. The Court is respectfully referred to the administrative record for a full and
21 accurate statement of their contents.

22 59. Admitted that the late Plaintiff's claims were denied on redetermination,
23 on the listed dates, and that she sought reconsideration. The remainder of this paragraph

1 consists of Plaintiff's characterization of those redetermination decisions, to which no
2 response is required. The Court is respectfully referred to the administrative record for a
3 full and accurate statement of their contents.

4 60. Admitted that the late Plaintiff's claims were denied on reconsideration,
5 on the listed dates, and that she sought review by an administrative law judge. The
6 remainder of this paragraph consists of Plaintiff's characterization of those
7 reconsideration decisions, to which no response is required. The Court is respectfully
8 referred to the administrative record for a full and accurate statement of their contents.

9 61. Admitted that the administrative law judge conducted a hearing and issued
10 a decision on the late Plaintiff's claims on the listed dates. The remainder of this
11 paragraph consists of Plaintiff's characterization of and quotation from that ALJ decision,
12 to which no response is required. The Court is respectfully referred to the administrative
13 record for a full and accurate statement of its contents.

14 62. This paragraph consists of a quotation from an administrative law judge's
15 decision on the coverage claim at issue in this case, to which no response is required.
16 The Court is respectfully referred to that ALJ decision for a full and complete statement
17 of its contents.

18 63. This paragraph consists of Plaintiff's characterization of filings before the
19 Medicare Appeals Council, to which no response is required. The Court is respectfully
20 referred to those filings for a full and complete statement of their contents.

21 64. Admitted that the Medicare Appeals Council issued a decision on the late
22 Plaintiff's claims on the listed date. The remainder of this paragraph consists of
23 Plaintiff's characterization of that decision, to which no response is required. The Court

1 is respectfully referred to the administrative record for a full and accurate statement of its
2 contents.

3 65. Admitted.

4 66. In this paragraph, Plaintiff repeats the paragraphs set forth above. The
5 Secretary incorporates by reference his answers to all of the preceding paragraphs as if
6 fully set out herein.

7 67. This paragraph consists of a request for relief, to which no response is
8 required. To the extent that a response is deemed necessary, the Secretary denies that
9 Plaintiff is entitled to the requested relief or any relief whatsoever.

10 68. This paragraph consists of a request for relief, to which no response is
11 required. To the extent that a response is deemed necessary, the Secretary denies that
12 Plaintiff is entitled to the requested relief or any relief whatsoever.

13 69. In this paragraph, Plaintiff repeats the paragraphs set forth above. The
14 Secretary incorporates by reference his answers to all of the preceding paragraphs as if
15 fully set out herein.

16 70. This paragraph consists of a request for relief, to which no response is
17 required. To the extent that a response is deemed necessary, the Secretary denies that
18 Plaintiff is entitled to the requested relief or any relief whatsoever.

19 71. This paragraph consists of a request for relief, to which no response is
20 required. To the extent that a response is deemed necessary, the Secretary denies that
21 Plaintiff is entitled to the requested relief or any relief whatsoever.

22 72. In this paragraph, Plaintiff repeats the paragraphs set forth above. The
23 Secretary incorporates by reference his answers to all of the preceding paragraphs as if

1 fully set out herein.

2 73. This paragraph consists of a request for relief, to which no response is
3 required. To the extent that a response is deemed necessary, the Secretary denies that
4 Plaintiff is entitled to the requested relief or any relief whatsoever.

5 74. This paragraph consists of a request for relief, to which no response is
6 required. To the extent that a response is deemed necessary, the Secretary denies that
7 Plaintiff is entitled to the requested relief or any relief whatsoever.

8 75. In this paragraph, Plaintiff repeats the paragraphs set forth above. The
9 Secretary incorporates by reference his answers to all of the preceding paragraphs as if
10 fully set out herein.

11 76. This paragraph consists of a request for relief, to which no response is
12 required. To the extent that a response is deemed necessary, the Secretary denies that
13 Plaintiff is entitled to the requested relief or any relief whatsoever.

14 77. This paragraph consists of a request for relief, to which no response is
15 required. To the extent that a response is deemed necessary, the Secretary denies that
16 Plaintiff is entitled to the requested relief or any relief whatsoever.

17 78. In this paragraph, Plaintiff repeats the paragraphs set forth above. The
18 Secretary incorporates by reference his answers to all of the preceding paragraphs as if
19 fully set out herein.

20 79. This paragraph consists of a request for relief, to which no response is
21 required. To the extent that a response is deemed necessary, the Secretary denies that
22 Plaintiff is entitled to the requested relief or any relief whatsoever.

23 80. This paragraph consists of factual allegations regarding continuous

1 glucose monitors. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court's review in this
2 action is based solely on the administrative record, rather than the allegations of the
3 parties in their respective pleadings; Defendant thus respectfully refers the Court to the
4 administrative record for a full and accurate statement of its contents. To the extent that
5 these allegations are not reflected in the administrative record, they are beyond the scope
6 of the Court's review in this case, and no response is required.

7 81. This paragraph consists of a request for relief, to which no response is
8 required. To the extent that a response is deemed necessary, the Secretary denies that
9 Plaintiff is entitled to the requested relief or any relief whatsoever.

10 82. In this paragraph, Plaintiff repeats the paragraphs set forth above. The
11 Secretary incorporates by reference his answers to all of the preceding paragraphs as if
12 fully set out herein.

13 83. This paragraph consists of a request for relief, to which no response is
14 required. To the extent that a response is deemed necessary, the Secretary denies that
15 Plaintiff is entitled to the requested relief or any relief whatsoever.

16 84. This paragraph consists of a request for relief, to which no response is
17 required. To the extent that a response is deemed necessary, the Secretary denies that
18 Plaintiff is entitled to the requested relief or any relief whatsoever.

19 The remaining paragraphs of the complaint contain Plaintiff's requested relief, to
20 which no response is required. To the extent that a response is deemed necessary, the
21 Secretary denies that Plaintiff is entitled to the requested relief or any relief whatsoever.

22 The Secretary denies any and all allegations of the complaint not expressly
23 admitted herein.

1 **DEFENSES**

- 2 1. This Court lacks subject matter jurisdiction over Count IV and Count VI.
3 2. Count I fails to state a claim on which relief can be granted.
4 3. The Secretary's actions did not violate the Administrative Procedure Act,
5 the Medicare statute, or any other statutory or regulatory provision.

6

7 WHEREFORE, having fully answered, the Secretary respectfully request that the
8 Court enter judgment dismissing this action with prejudice and awarding the Secretary
9 costs and such other relief as the Court may deem appropriate.

Respectfully submitted this 1st day of May, 2020,

JOSEPH H. HUNT
Assistant Attorney General

MICHELLE BENNETT
Assistant Director, Federal Programs Branch

/s/ James Bickford
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